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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,992	01/22/2004	Maurice Cohen	5967.US.C1	8330
23492	7590	04/19/2006	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/763,992

Applicant(s)

COHEN ET AL.

Examiner

Laura B. Goddard, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. The Amendment filed January 23, 2006 in response to the Office Action of July 21, 2005, is acknowledged and has been entered. Applicants confirmed election of Group I, claims 1-9 and SEQ ID NO:9 made without traverse. Previously pending claims 1-3 and 6 have been amended. Claims 1-9 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **New Grounds for Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "said target-specific polynucleotide". There is insufficient antecedent basis for this limitation in the claim.
4. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "a method of detecting the presence

Art Unit: 1642

of prostate cancer associated (PS112) polynucleotide in a test sample" and "wherein said target-specific polynucleotide specifically hybridizes to said test sample". It is unclear if the target-specific polynucleotide is hybridizing to the test sample itself, or the PS112 polynucleotide in the test sample. The specification describes a test sample as a component of an individual's body which is the source of the analyte of interest and anything suspected of containing a target sequence (p. 16, lines 31-36). It is unclear how the target-specific polynucleotide would hybridize to a test sample if it did not contain the target polynucleotide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 2 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation "wherein said target-specific polynucleotide specifically hybridizes to said test sample" has no clear support in the specification and the claims as originally filed. THIS IS A NEW MATTER REJECTION.

Applicant points to page 24, line 19 through page 25, line 12 and page 26, lines 8-36 to support the newly added claim limitation "wherein said target-specific polynucleotide specifically hybridizes to said test sample". However, a review of page 24, line 19 through page 25 reveals support for the polymerase chain reaction (PCR) where a pair of primers are employed in excess to hybridize to the complementary

Art Unit: 1642

strands of the target nucleic acid, Ligase Chain Reaction (LCR) where probes are used to hybridize to a target strand and the probes are ligated into a fused product, and amplification of mRNA. A review of page 26, lines 8-36 reveal support for detection, both heterogeneous and homogeneous detection formats, use of multiple probes in a hybridization assay, and description of steps of the invention comprising contacting a test sample suspected of containing a target polynucleotide sequence with amplification reaction reagents comprising an amplification primer and a detection probe that can hybridize with an internal region of the amplicon sequences.

The cited support has been considered but has not been found persuasive because the cited support is not drawn to a target-specific polynucleotide that specifically hybridizes to said test sample. Although the specification teaches methods of polynucleotide amplification and detection comprising probes and primers that hybridize to complementary strands of a target sequence, the specification neither states nor demonstrates **a target-specific polynucleotide specifically hybridizing to said test sample.**

### **Maintained Rejection**

#### ***Double Patenting***

6. Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No.

6,110,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the US Patent and instant application are

Art Unit: 1642

drawn to the methods of detecting the presence of PS112 polynucleotide and mRNA of PS112 in a test sample.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to a method of detecting the presence of a target prostate cancer associated (PS112) polynucleotide in a test sample comprising contacting said test sample with at least one target-specific polynucleotide or full complement thereof and detecting the presence of said target polynucleotide in the test sample, wherein said target-specific polynucleotide specifically hybridizes to said test sample and is selected from the group consisting of SEQ ID NOs:1-10, which anticipates the genus of method in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Examiner notes that Applicants will submit a Terminal Disclosure upon notice by the Patent Office of allowable subject matter.

7. All other rejections and objections recited in the Office Action mailed July 21, 2005 are hereby withdrawn.

8. No claim is allowed.

Art Unit: 1642

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**